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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,464	10/18/2001	William D. Huse	AME-06381	7635

25885 7590 02/25/2005
ELI LILLY AND COMPANY
PATENT DIVISION
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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

H/C

Office Action Summary	Application No. 09/982,464	Applicant(s) HUSE ET AL	
	Examiner Larry R. Helms	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-10,12-16,18-22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-10,12-16,18-22 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. No claims have been amended.
2. The text of those sections of title 35, USC Code not included on the Office Action can be found in a prior Office Action.

Response to Arguments

3. The rejection of claims 1-4, 6-10, 12-16, 18-22 and 24 under 35 U.S.C. 103(a) as being unpatentable over Jones et al (Nature 321:522, 1986) and further in view of Yelton et al (The Journal of Immunology 155:1994-2004, 1995) and Soderlind et al (Gene 160:269-72, 1995) and Hagiwara et al (U.S. Patent 5,589,573, issued 12/96) is maintained.

The response filed 12/13/04 has been carefully considered but is deemed not to be persuasive. The response argues that Soderlind teaches away by teaching specific human framework or a master framework (in the gene 1998 paper). In response to this argument, the gene 1998 paper is irrelevant because it is not in the rejection. With regard to the Soderlind 1995 paper used in the rejection, the reference does not teach away. The reference is used in the rejection to teach libraries of variable domains wherein the CDRs are mutagenized and the frameworks were unchanged and the libraries were made by overlapping oligos (see entire document). The claims only

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require that the frameworks be unmodified and that there is only a reference human acceptor framework. There is nothing in the claims requiring diverse unmodified framework as recited in the response on page 6, lines 6-7. It would have been obvious to use an unmodified framework as recited in the claims based on Soderlind because Soderlind et al used an unmodified framework region for the library and modified the CDRs. In addition, Jones used an unmodified human framework for CDR grafting. The advantages of using overlapping oligos was taught by Soderlind as allowing the construction of the library in one single PCR reaction (see abstract). Thus there would be an advantage to use this technique.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

4. The rejection of claims 1-4, 6-10, 12-16, 18-22 and 24 under 35 U.S.C. 103(a) as being unpatentable over Jones et al (Nature 321:522, 1986) and further in view of Wu et al (PNAS 95:6037-6042, 5/98) and Soderlind et al (Gene 160:269-72, 1995) and Hagiwara et al (U.S. Patent 5,589,573, issued 12/96) is maintained.

The response filed 12/13/04 has been carefully considered but is deemed not to be persuasive. The response argues that Soderlind fails to support an obvious rejection for the reasons above (see page 7 of response). In response to this argument, the same response as above is reiterated here.

Conclusion

5. No claim is allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The

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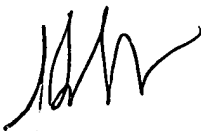
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faxing of such papers must conform with the notice published in the Official Gazette,
1096 OG 30 (November 15, 1989). The Fax Center telephone number is 571-273-
8300.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D
PRIMARY EXAMINER